The Pay-for-Delay Dilemma: Changes and Challenges Are on the Horizon for Innovative Pharmaceutical Companies

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Settlement of patent litigation on pharmaceutical inventions, especially so-called "pay-for-delay" settlements, have attracted significant attention recently.

Pay-for-delay, a controversial business practice, involves two drug companies—an innovative pharmaceutical company (a brand company in the "pay-for-delay" context) and a generic company. The brand company pays the generic company not to challenge the patent that covers the brand company's drug, to stay out of the market, and to settle litigation brought under the Hatch-Waxman Act.

Some interest groups claim that banning pay-for-delay will reduce prescription drug prices and speed the entry of generics onto the market. Others argue that not allowing these types of settlements could harm innovation and hinder the development of new drug products.

The Supreme Court

Challengers to pay-for-delay settlements have sought recourse in the Supreme Court. Louisiana Wholesale Drug Co. Inc. v. Bayer AG, No. 10-762, is the latest in a string of lawsuits challenging "pay-for-delay" settlement, but the Supreme Court declined to hear the case March 7.

The facts are simple. The antibiotic ciprofloxacin (Cipro) is one of Bayer's best-selling drugs. Barr Laboratories submitted an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration (FDA). To satisfy the ANDA requirements, Barr certified that the Cipro patent was invalid or would not be infringed by Barr's making, using, or selling a generic version of Cipro. Bayer sued Barr.

Two weeks before the trial in 1997, Bayer settled with Barr. In exchange for Barr's promise to stay out of all but the last six months of the remaining patent term, Bayer agreed to pay $398 million.

Louisiana Wholesale Drug Co., along with three other drug wholesalers, sued Bayer and Barr for violating the antitrust law. The district court found for Bayer on the ground that the antitrust law is not violated as long as the patent was not procured by fraud or the patent suit was not a sham. The appellate court twice affirmed the district court's ruling, and Louisiana Wholesale Drug Co. petitioned the Supreme Court for a further review, which the court declined.

Undeterred by the Supreme Court's refusal, challengers to pay-for-delay agreements have sought recourse from Congress. On Jan. 25, Congress reintroduced a bill to "prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market."

This bill, if passed, creates a rebuttable presumption that any pay-for-delay agreement is anticompetitive and, thus, unlawful if the generic company receives anything of value and agrees to limit or forego research, development, manufacturing, marketing, or sales of the generic drug for any period of time.

In order to rebut this presumption, the parties to the agreement must demonstrate by clear and convincing evidence—a fairly high burden of proof—that the precompetitive benefits of the agreement outweigh the anticompetitive effects.

In addition, this bill also gives the Federal Trade Commission (FTC) the authority to enforce this bill and to fine the "pay-for-delay" parties up to three times the value received by the brand company or the value given to the generic company reasonably attributable to the violation. If enacted, this legislation would significantly hinder companies' ability to settle pharmaceutical patent litigation.

On Feb. 14, facing challenges on increasing prescription drug prices, the White House submitted its proposed budget for the fiscal year 2012 for congressional approval. In this budget proposal, President Obama proposed to increase the availability of generic drugs by providing the FTC authority to stop drug companies from entering into pay-for-delay agreements.

Pay-for-delay settlements raise difficult questions that require balancing competing policy issues. On one hand, patents are critical for the pharmaceutical industry to invest in new drug discovery and development, and on the other, the cost of new drugs presents significant economic challenges to individuals, insurance companies, and the government. As a result, various industry organizations, political groups, and government groups take diametrically opposite positions. While the FTC treats any pay-for-delay agreements as anticompetitive, the Cipro court held that they do not violate the antitrust law as long as the anticompetitive effects are within the exclusionary power of the patent that covers the drug.

Battle Lines Drawn

However, the exclusionary power of pharmaceutical patents is particularly important to encourage innovative pharmaceutical companies to invest in drug discovery and development. The process of finding, developing, and obtaining marketing approval for a drug is lengthy, costly, and

unpredictable. Recent studies show that it takes an average of 10 to 15 years and approximately $1.3 billion for a pharmaceutical company to develop a new drug, partially because of the low success rate in this industry. Only one out of 5,000 compounds tested is eventually approved by the FDA. In 2007, pharmaceutical companies invested about $60 billion in research and development. In addition, only about 20% to 30% of these approved drugs recoup their initial investment.

Considering both of the laws that encourage innovation and competition, the Cipro court affirmed the lower court's decision that the pay-for-delay practice should not be banned outright, stating: "Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent."

In contrast, one primary reason asserted for banning pay-for-delay settlements is that they give pharmaceutical patents more exclusionary power than they should have. In order for a brand company to exclude a generic company from selling a generic version of the brand drug, the brand company must prove that the patent covering the drug is valid and will be infringed by the generic's ANDA filing.

While acknowledging that an agreement is within the exclusionary power of a patent if it is based on the patent being found valid and infringed, some have argued that a similar agreement is not justified if the validity or infringement of the patent is untested in litigation. Opponents of pay-for-delay argue that litigation is a more appropriate vehicle to resolve whether the patent is valid and infringed than a pay-for-delay agreement, where a generic company simply concedes the validity and infringement.

Further, some argue that the generic company's concession of the validity and infringement of the innovation patent is not justified by the "extremely poor" quality of patents in the U.S. A University of Houston Law School study showed that approximately 45% of all patents reviewed by courts in 2009 were found to have been undeserved. In addition, when challenged in the United States Patent and Trademark Office, 95% of patents have their claims canceled or changed. More importantly, studies show that 70% to 73% of fully litigated pharmaceutical patents were found either invalid or not infringed. Thus, allowing generic companies to simply concede the validity and infringement of pharmaceutical patents in "pay-for-delay" agreements would likely give these patents more exclusionary power than they truly deserve.

Opponents cite the ever-rising cost of prescription drugs as another important policy reason for banning the pay-for-delay practice. A generic drug costs substantially less than the corresponding brand drug, with discounts off the brand prices sometimes exceeding 90%.

However, for a generic drug to enter into the market, the generic company must survive a near certain Hatch-Waxman litigation. Facing the high cost and the uncertainty of the outcome of the litigation, both the brand company and its generic counterpart have the incentive to settle out of court. As part of the settlement, the brand company usually pays the generic company and, in exchange, the generic company agrees not to enter into the market for a certain period of time. The

proposed legislation argues that the Hatch- Waxman Act has been "subverted" by these settlement agreements, delaying the marketing of lower-cost generic drugs and benefiting both brand and generic manufacturers at the expense of consumers. The lost benefits for consumers are estimated to be between $3.5 billion and $14 billion annually.

Banning the pay-for-delay practice has a broad appeal among many constituencies. Proponents include drug wholesalers, attorney generals of 34 states, law professors, and advocacy groups, including Consumer Federation of America, the Prescription Access Litigation Project, the National Legislative Association on Prescription Drug Prices, U.S. PIRG (the Federation of State Public Interest Research Groups), the American Association of Retired Persons, the American Antitrust Institute, National Association of Chain Drug Stores Inc., and the Public Patent Foundation.

Banning the pay-for-delay practice may be shortsighted, however. While consumers would enjoy the added availability and low prices of generic drugs in the short term, they might have to suffer from lack of new drugs and therapies in the long run as the U.S. pharmaceutical industry loses its competitive edge.

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